

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | | | | | | | | | | | | | | | | | |
|--|---|--|---|---------------------|-------------------------------------|----------|--------------------------------------|--|-------------------------------------|----------------------------|---|---|--|-------------------------|---|--|---------------------------------------|---|
| Applicant's or agent's file reference bom025678pc | FOR FURTHER ACTION See Form PCT/IPEA/416 | | | | | | | | | | | | | | | | | |
| International application No. PCT/DK 2003/000680 | International filing date (day/month/year) 09.10.2003 | Priority date (day/month/year) 09.10.2002 | | | | | | | | | | | | | | | | |
| International Patent Classification (IPC) or national classification and IPC A61B 7/04, G06F 17/00 | | | | | | | | | | | | | | | | | | |
| Applicant Bang & Olufsen Medicom A/S et al | | | | | | | | | | | | | | | | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>3</u> sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table border="0" style="width: 100%;"> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | | | <input checked="" type="checkbox"/> Box No. I | Basis of the report | <input type="checkbox"/> Box No. II | Priority | <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input checked="" type="checkbox"/> Box No. VI | Certain documents cited | <input checked="" type="checkbox"/> Box No. VII | Certain defects in the international application | <input type="checkbox"/> Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> Box No. I | Basis of the report | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Box No. II | Priority | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Box No. VI | Certain documents cited | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Box No. VII | Certain defects in the international application | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application | | | | | | | | | | | | | | | | | |
| Date of submission of the demand 08.05.2004 | Date of completion of this report 08.11.2004 | | | | | | | | | | | | | | | | | |
| Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88 | Authorized officer Anna Malmberg /OGU Telephone No. +46 8 782 25 00 | | | | | | | | | | | | | | | | | |

Form PCT/IPEA/409 (cover sheet) (January 2004)

BEST AVAILABLE COPY

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International Application No.

PCT/DK 2003/000680

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 3-17 as originally filed/furnished

pages* 1, 2, 2a received by this Authority on 20.09.2004

pages* _____ received by this Authority on _____

☒ the claims:

pages 18-20 as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the drawings:

pages 1-5 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | | |
|-------------------------------|--------|------------|-----|
| Novelty (N) | Claims | <u>1-9</u> | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | <u>1-9</u> | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | <u>1-9</u> | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

This report is based on the claims as originally filed.

Prior art

Reference is made to the following documents:

D1: Haghighi-Mood, A. et al. "A sub-band energy tracking algorithm for heart sound segmentation", Computers in Cardiology 1995, Vienna, Austria, 10-13 Sept. 1995, pages 501-504.

D2: Huiying, L. et al. "A heart sound segmentation algorithm using wavelet decomposition and reconstruction", ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY, 1997. PROCEEDINGS OF THE 19TH ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE, Chicago, IL, USA, 30 October - 2 November 1997, Vol. 4, pages 1630-1633.

D3: SHINO, H. et al. "Phonocardiogram classification using time-frequency representation". In: ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY, 1997. PROCEEDINGS OF THE 19TH ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE, Chicago, IL, USA, 30 October - 2 November 1997, Vol. 4, pages 1636-1637.

D4: US 5685317 A

Document D1 discloses a method for energy tracking of heart sounds which can be used for non-invasive detection of heart diseases.

Document D2 discloses a method for automatic segmentation of heart sound. It is possible to isolate desired events in subjects with various pathological conditions.

Documents D3-D4 merely represent common prior art.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

Statement of reason

The claimed invention according to claims 1-9 relates to a procedure for extracting information from a phonocardiographic signal, an apparatus for performing the procedure and a procedure for extracting murmur information.

In the method in D1 the heart sound signals are extracted with the use of synchronizing information from electrocardiographic signals. Document D1 does not teach to extract information only from a heart sound signals such as a phonocardiographic signal according to claim 1.

Document D2 does not teach any signal processing procedure containing energy distribution over time. The processing procedure in D2 does not include any bandpass filtering, followed by instantaneous power and low-pass filtering of the original phonocardiographic signal corresponding to the processing according to claim 1.

The invention according to claims 1-9 is thus novel and is considered to involve an inventive step. The invention according to claims 1-9 is industrially applicable.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/DK 2003/000680

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

| Application No. Patent No. | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (valid claim) (day/month/year) |
|-------------------------------|--------------------------------------|---------------------------------|---|
| WO 02096293 A1 | 05.12.2002 | 28.05.2002 | 28.05.2001 |

2. Non-written disclosures (Rule 70.9)

| Kind of non-written disclosure | Date of non-written disclosure (day/month/year) | Date of written disclosure referring to non-written disclosure (day/month/year) |
|--------------------------------|--|---|
|--------------------------------|--|---|

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/DK 2003/000680

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 8 is assumed to refer to claim 7 and not to claim 6.

A procedure for extracting information from a heart sound signal.

- 5 The invention relates to a procedure for extracting information from a
phonocardiographic signal obtained from a transducer and subjected to signal
processing in order to aid evaluation and diagnosis of heart conditions. The invention
furthermore relates to techniques forming part of such extraction and apparatus to
perform such feature extraction as well as coding the features to aid the ability to
10 distinguish between related features.

Signals obtained by means of a transducer are phonocardiographic representations of
sounds traditionally listened to by means of a stethoscope. Training in auscultation
takes a long time and requires an aptitude for recognising and classifying aural cues,
15 frequently in a noisy environment. 20-30 different conditions may need to be
differentiated, and within each, the severity evaluated. Furthermore, there may be
combinations among these. These factors contribute to explaining why not all
physicians perform equally well when diagnosing heart conditions, and why it may
be time-consuming.

20

The so-called first (S1) and second (S2) heart sound are very important markers in
the assessment of a heart sound signal. These sounds are directly related to the
functioning of the heart valves, in that S1 is caused by the closure of the
atrioventricular valves and contraction of the ventricles and S2 is caused by the
25 closure of the aortic and pulmonary valves.

It has been tried to use further signals derived from ECG signals to determine the
points in time during which to expect specific heart sounds, such as US 5,685,317,
and as described in Haghighi-Mood, A. et al. "A sub-band energy tracking algorithm
30 for heart sound segmentation", In: Computers in Cardiology 1995, Vienna, Austria,
10-13 September 1995, pp. 501-504, which latter is model-based (AR). The extra
complication of using ECG in addition to phonocardiographic signals is not generally
desirable.

A number of patents relate to the extraction of the S1 and S2 signals, such as US 6,048,319, which concerns the measurement of the time interval between the S1 and S2 signals in relation to the heart rate in order to determine the degree of coronary artery disease. The measurement is based on peak detection and autocorrelation and it may be considered a relatively slow process.

In order to determine the occurrence of the first and second heart sounds a wavelet analysis and re-synthesis and various time occurrence manipulations are used in Huiying, L. et al. "A heart sound segmentation algorithm using wavelet decomposition and reconstruction", ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY, 1997. PROCEEDINGS OF THE 19TH ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE, Chicago, IL, USA, 30 October - 2 November 1997, Vol.4, pp. 1630-1633. It is described as being a good basis for further analysis of heart sound signals.

15

In WO 02/096293 A1a complex procedure is described, comprising the use of wavelets, calculating the signal's Shannon's energy, calculating the area of each of a number of energy envelopes, and performing cluster analysis. The latter is needed to identify the S1 and S2 signals, but it is a complicated procedure, and the output of the complex procedure is a number of diagnoses, including murmur.

20

A different category of signals related to various heart conditions is generally known as murmurs. The known procedures of isolating and categorizing murmurs are generally dependent on the simultaneous recording of electrocardiographic data, such as US 5,957,866 and US 6,050,950 and this complicates the practical use of auscultation techniques considerably.

25

The above solutions are very complex and rely on techniques that are equivalent to a long averaging time. According to the invention a method has been derived which is more precise and obtains a faster result. This is obtained by a sequence of steps, comprising an optional adaptive noise reduction, detection of S1 and S2, e.g. by means of the feature extraction procedure mentioned above, enhancement of the signal by elimination of the S1 and S2 contributions, performing spectral analysis and feature enhancement in order to obtain the energy content present in areas of a

30

time-frequency representation delimited by frequency band times time interval in the form of energy distributions, classifying the energy distributions according to pre-defined criteria, and comparing the energy distributions to a catalogue of distributions related to known medical conditions and extracting information by
5 comparing the enhanced signal to stored time functions.

According to the present invention the detection of S1 and S2 is obtained by performing the steps of feature extraction and classification based on the energy distribution over time in a feature time function. The feature extraction is performed
10 by the steps of bandpass filtering, followed by instantaneous power and lowpass filtering. This generates a series of signal peaks or "hills", each relating to either an S1 or an S2, and a signal classification step determines which "hill" is to be regarded as either an S1 or an S2, whereby a systole is correctly identified.

15 The correct placement in time of S1 and S2 permits the energy relating to these sounds to be eliminated in the signal processing, and the resulting sound (including murmurs, etc.) is a useful starting signal for further analysis, because it increases the dynamic range of the remaining signal. It also permits presenting the remaining signal to the ears with a superposition of correctly placed but "neutral" S1 and S2
20 contributions as mere time markers, but without any signal that the listener needs to process in the listening process.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.